IN THE CLAIMS

Please add new claims 68 and 69.

1. (Currently Amended) A catheter adapted for deployment in a body vessel to occlude flow and remove material located distal to a site of occlusion, comprising:

an outer elongated hollow shaft configured for introduction into a blood vessel,

an expandable occluder proximate to a distal end of the outer shaft, which expands to create a distal occlusion within the vessel to isolate a region proximal of the occluder from vasculature distal of the occlusion,

an efflux port in fluid communication with an outer shaft lumen that provides for the removal of fluid and material ~~from the distal vasculature~~ through an opening distal of the distal occlusion,

an inner elongated and hollow shaft configured to slide longitudinally within the outer shaft and extending distal of the distal occlusion, wherein the inner shaft terminates in a rinse head~~nozzle~~ having one or more rinse holes~~openings~~ that traverse a side wall of the rinse head to force ~~allow the~~ fluid contents of an inner shaft lumen ~~to enter the distal vasculature~~ through the one or more rinse holes~~openings vessel~~ in the region distal of the expandable occluder ~~and~~ in a flow pattern determined by the arrangement of the one or more ~~openings~~ rinse holes and directed toward side walls of the body vessel,

an influx port in fluid communication with the inner shaft lumen, and

a treatment port that provides access to the lumen of the outer shaft.

2. (Previously Presented) The device of claim 1, wherein the expandable occluder is inflatable and is connected to an inflation lumen incorporated into a wall of the outer elongated shaft.

3. (Previously Presented) The device of claim 1, wherein the expandable occluder is inflatable and is connected to an inflation lumen extending through a separate, hollow elongated shaft that runs parallel to the outer shaft.

4. (Cancelled)

5. (Previously Presented) The device of claim 1, wherein the inner shaft is configured to allow passage of a guidewire through the inner shaft lumen and that extends through an opening in the distal wall of the inner shaft, for the purposes of aiding in the delivery of the catheter and treatment or diagnostic means to the site of interest within a blood vessel.

6. (Original) The device of claim 1, wherein the expandable occluder is self-expanding.

7. (Previously Presented) The device of claim 1, wherein the expandable occluder comprises open-cell foam surrounded by an airtight sheath and the open-cell foam is in fluid communication with an inflation lumen incorporated into the wall of the outer shaft.

8. (Previously Presented) The device of claim 1, wherein the expandable occluder comprises open-cell foam surrounded by an airtight sheath and the open-cell foam is in fluid communication with an inflation lumen in a separate, hollow elongated shaft that runs parallel to the outer shaft.

9. (Original) The device of claim 1, further comprising means for varying rates of fluid flow through the influx port and/or the outflux port over time in a manually controlled or programmed fashion.

10. (Original) The device of claim 1, further comprising means for inducing fluid flow within the vessel at or near the treatment site at physiologically relevant flow levels.

11. (Previously Presented) The device of claim 1, further comprising a stent delivery catheter introduced through the treatment port and the outer shaft lumen.

12. (Previously Presented) The device of claim 1, further comprising an angioplasty catheter introduced through the treatment port and the outer shaft lumen.

13. (Previously Presented) The device of claim 1, further comprising a filter introduced through the treatment port and the outer shaft lumen.

14. (Cancelled)

15. (Previously Presented) The device of claim 1, wherein the inner shaft lumen is sized and configured for passage of a guidewire.

16. (Previously Presented) The device of claim 1, wherein the inner shaft lumen is terminated on a distal end by a flexible seal configured to allow passage of a guidewire and to form a fluid tight seal around the guidewire.

17. (Original) The device of claim 1, further comprising a guidewire fixedly attached to a distal end of the inner shaft.

18-33. (Cancelled)

34. (Currently Amended) A catheter adapted for deployment in a body vessel to occlude flow and provide fluid exchange distal to an occlusion, comprising:

an outer elongated and hollow shaft configured for introduction into a blood vessel,

an expandable occluder proximate to a distal end of the outer shaft which expands to create a distal occlusion within the vessel that isolates a region proximal of the occluder from vasculature distal of the occluder,

an efflux port in fluid communication with an outer shaft lumen that provides for the removal of fluid and material from the vasculature distal of the distal occlusion through an opening distal of the occluder,

an inner elongated and hollow shaft configured to slide longitudinally within the outer shaft and lacking an expandable occluder, wherein the inner shaft terminates in a rinse head havinghas one or more rinse holes that traverse a side wall of the rinse head to forceopenings proximate to a distal end thereof that allow fluid contents ofwithin an inner shaft lumen to enter the vessel in the region distal of the expandable occluder in a flow pattern determined by the arrangement of the one or more rinse holesopenings and directed toward side walls of the body vessel, and

an influx port in fluid communication with the inner shaft lumen.

35. (Currently Amended) The device of claim 34, further comprising:

a treatment port that provides access to a lumen of the outer shaft.

36. (Original) The device of claim 34, wherein the at least one opening comprises a multiplicity of openings, the openings being angled in a proximal direction with respect to a longitudinal axis of the inner shaft.

37. (Previously Presented) The device of claim 34, wherein the expandable occluder is inflatable and is connected to an inflation lumen incorporated into a wall of the outer shaft.

38. (Original) The device of claim 34, wherein the expandable occluder is inflatable and is connected to an inflation lumen extending through a separate, hollow elongated shaft that runs parallel to the outer shaft.

39. (Cancelled).

40. (Previously Presented) The device of claim 34, further comprising a guidewire that extends through the inner shaft lumen and through an opening in a distal wall of the inner shaft.

41. (Original) The device of claim 34, wherein the expandable occluder is self-expanding.

42. (Previously Presented) The device of claim 34, wherein the expandable occluder comprises open-cell foam surrounded by an airtight sheath and the open-cell foam is in fluid communication with an inflation lumen incorporated into the wall of the outer shaft.

43. (Previously Presented) The device of claim 34, wherein the expandable occluder comprises open-cell foam surrounded by an airtight sheath and the open-cell foam is in fluid communication with an inflation lumen in a separate, hollow elongated shaft that runs parallel to the outer shaft.

44. (Previously Presented) The device of claim 34, further comprising means for varying rates of fluid flow through the influx port and/or the outflux port over time in a manually controlled or programmed fashion.

45. (Previously Presented) The device of claim 34, further comprising a source of radiopaque contrast agent in fluid connection with the inner shaft lumen.

46-66. (Cancelled)

67. (Currently Amended) The catheter of claim 1, wherein fluid communication between the inner shaft lumen and the rinse nozzle is configured to eject fluid along an entire distal length of an~~of the occluder and in contact with the~~ outer surface of the inner shaft~~along an entire distal length thereof~~.

68. (New) The catheter of claim 1 wherein the inner elongated and hollow shaft is the only lumen delivering fluid distal of the expandable occluder.

69. (New) The catheter of claim 34 wherein the inner elongated and hollow shaft is the only lumen delivering fluid distal of the expandable occluder.

The Basic Distinction Between the Present Invention and Johansson et al.

The new prior art reference used for the § 102(c) rejection, and the principal reference in each of the five § 103 rejections, of all the pending claims is the Johansson et al. reference. Applicants wish to inform the Examiner of other members of the Johansson et al. family submitted concurrently herewith in a new Information Disclosure Statement. Referring to the United States Patent Publication US 2001/0039411 A1, the specific member of the Johansson et al. family referred to by the Examiner in the final office action, the Examiner refers to Figures 6-10 as disclosing each element of the subject matter of the present claims. The entirety of the disclosure of Johansson et al. explicitly directed to Figures 6-10 is as follows:

> [0017] FIGS. 6 to 8 provides a representation of the various stages of the use of the total occlusion system of the subject invention.
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>
> [0018] FIGS. 9 and 10 provide views of alternative embodiments of the subject methods in which external energy is applied to the occlusion, e.g. by movement of a guidewire as shown in FIG. 9.
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> * * * *
>
> [0093] A representation of a target vascular site being flushed with both a dissolution fluid and an attenuating fluid according to this embodiment of the subject methods is provided in FIGS. 4 and 6. In FIG. 4, where the target lesion is a partial occlusion, a coaxial partial occlusion catheter device is introduced into the vascular site such that the balloon 46 of the partial occlusion insert 40 and the balloon 24 of the aspiration catheter 20 flank the partial occlusion 34. Dissolution fluid is introduced by the plurality of ports 44 on the partial occlusion insert. An attenuating solution is concomitantly introduced through annular space 45. Fluid is then removed from the vascular site by the aspiration catheter 20 through annular space 26. FIG. 6 provides a view of a total occlusion catheter insert flushing a vascular site 12 of a total occlusion 17. As can be seen in FIG. 6, dissolution fluid is

introduced through the central catheter and attenuating solution is introduced via the catheter immediately concentric with the center catheter. Fluid is removed from the vascular site via the aspiration catheter, in which the central and intermediate catheters are coaxially positioned. Another representation is provided in the Experimental Section, infra, which shows a dissolution agent concentration gradient which occurs in the vascular site during treatment according to the present invention.

* * * *

[0217] 4. The catheter device is inserted so that the distal end of the device is at the vascular site occupied by the total occlusion. The balloon is then inflated by depressing the syringe, such that the balloon occludes the vessel proximal to the occlusion. See FIG. 6.

* * * *

[0220] 7. The surface of the total occlusion is then flushed with both an acidic dissolution fluid A (0.1N HCl, 0.05 M NaCl) and a phosphate buffered saline solution at the same time as shown in FIG. 6.

* * * *

[0222] 9. Where desired, the balloon may be deflated, the entire device repositioned, and then balloon may be reinflated to move the distal end of the total occlusion catheter insert to a site further into the occlusion. See FIGS. 7 and 8.

* * * *

[0226] B. Variations on the Above Procedure

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[0227] The above procedure is performed with the additional step of applying mechanical energy to the occlusion during flushing with the acidic dissolution solution. FIG. 9 shows mechanical energy being applied to the occlusion by contacting a guidewire 91 with the surface of the total occlusion during flushing. FIG. 10 shows mechanical energy being applied to the surface of the occlusion with the proximal end of the total occlusion insert. Other means of applying external energy, e.g. mechanical energy, may also be employed.

The foregoing content of Johansson et al., which is the entirety of the discussion of Figures 6-10, shows that Johansson et al. is concerned with applying a force in the same direction as the longitudinal path of the catheter lumen to disrupt a total occlusion as pictured in Figures 6-10. This is achieved with two concentric catheters, each having a lumen for the delivery of fluid through a single opening at the absolute distal most (terminal) end of each catheter element. As is seen by the placement of the catheter relative to the "total occlusion," (the indication in which the "total occlusion" catheter of Figures 6-10 used) Johansson et al. uses fluid and mechanical force to target the total occlusion that is beyond the distal end of the device.

In contrast to Johansson et al., Applicants have provided the "rinse head" of the claims having "rinse holes" in the side wall thereof to direct fluid in a direction that is generally perpendicular to the fluid path of the lumen and is intended to establish flow along the internal vessel walls proximate to the rinse head – not beyond the distal-most point of the device as in Johansson et al.

The method of operation, and entire purpose of Johansson et al. would be contradicted by a deliberate attempt to provide for fluid delivery through an array of rinse holes that are directed in a direction that is generally perpendicular from the fluid flow path of the lumen of the catheter and is directed instead toward the vessel walls. Such an approach, which is the embodiment encompassed by the amended claims, literally contradicts the structure and purpose of Johansson et al. because an array configuration of such rinse holes in a rinse head would detract from the fluid flow that might otherwise be directed at the total occlusion in a manner consistent with the intent of the Johansson et al. device.

For these reasons, Applicants have amended the current claim set to recite that one or more rinse holes exist in a side wall of the rinse head and that these rinse holes are oriented to force the

fluid contents of the inner elongated and hollow shaft in a manner that is specifically directed to the side walls of the vessel in which the device of the present invention is placed. This amendment is reflected in both of the independent claims currently pending, namely claims 1 and 34.

Support for the present amendment is found in the specification in at least Figures 5A, 5B, 5C, 6, 7, 12, 13, 14, and 15 and the accompanying text wherein the perforations 152 are shown to be located on the rinse head 150 and to promote fluid flow in the direction of the vessel walls and that is generally perpendicular to the fluid path of the lumen. One particular embodiment of this aspect of the invention is shown in Figure 12, which further reinforces the distinction between the claimed subject matter and the Johansson et al. reference, where Figure 12 describes end cap 190 fitted at the most distal end of the rinse catheter. The structure function of the rinse cap in concert with the claimed plurality of rinse holes is directly contrary to the structure and spirit of the Johansson et al. reference and illustrate the difference between the fluid flow provided through a single port at the distal terminus of the inner catheters of Johansson et al. and through the rinse holes of the present invention. Referring to the end cap 190, the present specification states "this effectively prevents rinsing fluid from flowing out of the end hole 192 and forces it to flow out of the rinse holes or perforations 152 in the rinse head 150." As noted above, the mechanical structure of the present invention that dictates the specific direction of the rinse fluid flow from the inner lumen out the rinse holes 152 of the present invention, and directed to the side walls of a vessel in which the device of the invention is placed, completely distinguishes the structure of the Johansson et al. reference and renders it incapable of anticipating the present claims under § 102 and renders it inappropriate to be used in combination with other references cited as the basis for § 103 rejections.

A. Because the Structural Elements of the Rinse Holes and Rinse Head as Claimed are Not Disclosed by Johansson et al., This Reference Cannot Anticipate Under § 102(e).

In accordance with MPEP § 2131, "[a] claim is anticipated only if *each* and *every element* as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil of California, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). The disclosure of a claim element in a prior art reference, when relied upon to negate patentability, must also be clear and unambiguous. Further, "[t]he identical invention must be shown in as complete detail as contained in the...claim." Richardson v. Suzuki Motor Corp., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Furthermore, and uniquely important in this case is the requirement that the elements relied on in the prior art reference must be arranged as required by the claim. See In re Bonds, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990).

Specifically as to the § 102(e) rejections of claims 1-3, 5, 9-12, 15, 17, 34, 35, 37, 38, 40, 44, 45, and 67, the Johansson et al. reference contains only a brief disclose of a catheter where the infusion capability is provided by two lumens (essentially open-ended lumens) that each terminate in an opening that is structurally incapable of altering the direction of fluid flow towards side walls of a vessel. Thus, Johansson et al. lacks an element of the claimed invention, namely the rinse holes at the distal end of the lumen and in the rinse head as claimed. Lacking this limitation, the Johansson et al. reference cannot anticipate. The law is well settled that "[A] claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." Celeritas Techs. Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361, 47 U.S.P.Q.2d 1516, 1522 (Fed. Cir. 1998). The standard for lack of novelty, that is, for "anticipation," is one of strict identity. Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1296, 63 U.S.P.Q.2d 1597, 1600 (Fed. Cir. 2002).

Accordingly, the rejection of Claims 1-3, 5, 6, 9, 10-12, 15, 17, 34, 35, 40, 44, 45, and 67 under 35 U.S.C. § 102(e), as anticipated by Johansson et al is traversed by the amendment clarifying that the present claims define a structure providing fluid flow through the rinse holes in the rinse head and in the direction of the side of the vessel wall.

Applicants submit that Claims 1 and 34, as amended, as well as the claims that depend thereon are in condition for allowance and request such action accordingly.

A. Claim Rejections – 35 U.S.C. § 103

In accordance with MPEP § 2142, the Examiner bears the initial burden of establishing a *prima facie* case of obviousness. "To establish a *prima facie* case of obviousness, three basic criteria must be met." See MPEP § 2143. First, some suggestion or motivation in the prior art references or in the knowledge of one of ordinary skill in the relevant art must exist to modify or combine the references. Second, if the references are combined, a reasonable expectation of success must be shown. Then, finally, all of the claim limitations must be taught or suggested by one reference or a combination of references. Id.

With respect to the § 103 rejections, the distinguishing factors of Johansson et al. are described above. Calderon discloses a two-balloon system for isolating a portion of the vasculature for selective infusion and extraction of fluids, and for establishing an isolated circulation between the catheter system and the section of a vessel isolated by the two balloons. As noted in the previous amendment, in system of Calderon, a balloon is always present at a point more distal than the fluid exchange. Booth et al. merely disclose the utility of open cell foam in the environment of a catheter system that is fundamentally different that the subject matter of the present claims as amended. Although Macoviak describes a catheter with a sealed end surrounding a guidewire, the

fluid flow parameters of the claimed invention are readily distinguishable form the present claims. Tsugita describes the deployment of a filter, but no fluid exchange occurs distally of the distal occlusion and no rinse head or rinse holes of the present invention are disclosed.

The following sections are numbered according to the paragraphs of the final office action and address in detail each basis for rejection.

2. Claims 16 and 41 Are Not Rendered Obvious Because Calderon Does Not Disclose Fluid Exchange Distal of the Occluder and Because Calderon Cannot be Structurally Combined with Johansson et al. in a Manner that Retains Operability.

Calderon discloses structures for extraction and injection of agents distal to a proximate balloon but does not disclose fluid exchange distal of the second balloon. At column 7, lines 59-61, Calderon notes that, when used for retrograde perfusion, ports 25 and 31 are used for injection and extraction, respectively. Port 31 is clearly proximal of the occluder, balloon 22, and thus does not disclose the efflux port, efflux lumen and opening distal to the occluder.

For this reason, although Calderon has infusion and aspiration ports and occluding members to produce a fluid flow that is substantially along the vessel segment(s) within which the infusion catheter lies, the inclusion of the second, distal balloon (22) by Calderon renders the system completely incompatible with the embodiment of Johansson et al. cited against the present claims because the infused fluid in Calderon is on the opposite side of the distal occlusion balloon from the efflux port. Accordingly, a combination of Johansson et al. and Calderon must sacrifice either the fluid exchange compatibility distal of the occlusion or would achieve fluid exchange at a point between two balloons. Neither combination establishes a *prima facie* case against the pending claims.

Therefore, the combination of Calderon and Johansson et al. cannot be the basis of a § 103 rejection because, even in combination, the devices do not disclose the claimed elements of profusion occurring though the rinse holes of the rinse head and in the direction of the side wall of the body vessel combined with a fluid exchange distal of the occluder. The proposed combination applied to claims 6 and 41 is fundamentally flawed because the references cannot be functionally combined to create fluid exchange distal of the occluder and a *prima facie* case under 35 U.S.C. § 103 cannot be made based on the combination.

3. Claims 7, 8, 42, and 43 over Johansson et al. plus Booth

Claims 7, 8, 42, and 43 are rejected over Johansson et al. in combination with Booth et al. Claims 7 and 42 add the features of an open-cell foam in fluid communication with an inflation lumen incorporated into the wall of the outer shaft. Claims 8 and 43 define expandable open cell foam in fluid communication with the inflation lumen being in a separate, parallel shaft. While Booth et al. disclose an expanded cell foam that is constructed by exerting a vacuum through a lumen, it is not entirely clear that fluid communication is established. Even so, as above, the combination clearly does not disclose fluid exchange in a vessel distally of a distal occlusion in a manner such that fluid is forced through a plurality of rinse holes in a rinse head and directed against the vessel wall. It is respectfully submitted that a *prima facie* case under § 103 cannot be established under this combination because neither reference teaches or suggests a catheter device of this aspect of the catheter as claimed.

4. Claims 13 over Johansson et al. in view of Tsugita.

Claim 13 depends from claim 1 and specifies the separate use of a filter introduced through the outer shaft lumen. Tsugita does not cause the deficiencies of Johansson et al. with respect to the combination of fluid exchange distal of the occluder and the specific director of fluid flow through the rinse holes and rinse head even in a literal combination of the Tsugita system with Johansson et al. Without acquiescence in the propriety or operability of the combination, Applicants submit that a prima facie case under § 103 is not established against the amended claims for the same reasons as cited above.

5. Claim 16 over Johansson et al. plus Macoviak

While Macoviak et al. appears to disclose the option of sealing the distal end around a guidewire, the combination with the device of Johansson et al. with Macoviak still would not yield the claimed elements of the present invention because the resulting combination does not yield a mechanism for fluid exchange distal of the occlusion, through the rinse head and holes and directed toward the vessel walls. It appears that the primary disclosure of Macoviak et al. is intended to supply selective perfusion in the aortic arch, and while a distal occlusion is one professed alternate, no distal perfusion through a rinse head at the distal end of an inner shaft lumen is contemplated. Thus, even assuming that a combination of Johansson et al and Macoviak were operative, the combined device would not feature each element at the claims. Therefore, no prima facie case exists under § 103.

Finally, Applicants note the absence of any rationale in the cited references that could lead to a modification of a reference or any combination thereof that would render the present claims unpatentable under § 103. The present claimed invention is different from the "total" occlusion

system suggested by Johansson et al. for the reasons stated above. Any combination with Booth, Macoviak, or Tsugita attempts to merge distal fluid exchange with fluid exchange proximal of an occluder. These combinations are structurally incompatible and would violate the intent of Johansson et al. to apply mechanical or fluid force to an occlusion located beyond the distal-most portion of the device.

Accordingly it is submitted that pending claims, as amended, are believed to be in condition for allowance.

If a telephone call would further prosecution of this case, the Examiner is invited to call the undersigned attorney at (949) 567-6700, extension 7740.

The Applicant's attorney of record hereby authorizes the Commissioner to charge any amounts due in the above-identified application to Orrick, Herrington & Sutcliffe's Deposit Account No. **150665** and to credit any overpayments to said Deposit Account No. **150665.**

Respectfully submitted,

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Dated: May 7, 2004

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